K014213
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JAN 17 2002

1. 510(k) SUMMARY

as required per 807.92(c)

Submitters Name, Address:

Siemens Medical Solutions, Inc.
Electromedical Systems Group, PCS
Danvers, MA 01923
Tel: (978) 907-7500
Fax: (978) 750-6879
Establishment Registration Number: 1220063
Official Correspondent: Connie Hertel, Director, QA/RA
Contact person for this submission: Penelope H. Greco
Date submission was prepared: December 20, 2001

Trade Name, Common Name and Classification Name:

A. Trade Name:
INFINITY Gateway Suite

B. Common Name, Classification Name, Class and Regulation Number:

Common Name	Product Code	Class	Regulation Number
System, Network and Communication, Physiological Monitors	MSX		
Computers and Software, Medical	LNX		

Legally Marketed Device Identification:

K955059 Olympus Communications Network, SC 3000 WorkStation and Remote Display

Device Description:

The Infinity Gateway Suite is a server-based software application that provides a connection to the Infinity Network (K955059) and the hospital network infrastructure for the data exchange of select clinical and administrative information. The Infinity Gateway complies with healthcare information protocols to support data sets of many different sources, including medical devices, hospital information systems, clinical information systems, and laboratory systems.

Infinity Gateway includes a suite of software products to support the unique needs of hospitals, and provide a complete range of options for information connectivity:

- Server Software
- Interface Software Options
- Developers Tools
- Remote View Applications

Intended Use:

Siemens MultiView WorkStation, INFINITY Network and remote display are intended to act as a central monitoring device, communications network, and remote display for Siemens INFINITY Patient Monitoring Systems and recorders. The INFINITY Gateway Suite is intended to provide clinicians with the capability of viewing patient data remotely via the INFINITY Network and the hospital network infrastructure for the data exchange of select clinical and administrative information. The INFINITY Gateway is not patient connected.

Assessment of non-clinical performance data for equivalence: Section J

Assessment of clinical performance data for equivalence: Not applicable

Biocompatability: Not applicable

Sterilization: Not applicable

Standards and Guidances: Section E

Siemens Medical Systems, Inc.
Electromedical Systems Group, PCS
16 Electronics Avenue
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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 1 7 2002

Ms. Penelope H. Greco
Regulatory Submissions Manager
Siemens Medical Solutions, Inc.
Electromedical Systems Group, PCS
16 Electronics Avenue
Danvers, MA 01923

Re: K014213
Trade Name: INFINITY Gateway Suite
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia Detector and Alarm
Regulatory Class: Class III (three)
Product Code: MHX
Dated: December 20, 2001
Received: December 21, 2001

Dear Ms. Greco:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

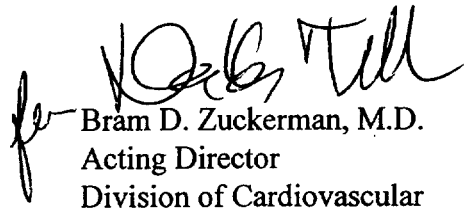
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4645. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



for Bram D. Zuckerman, M.D.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K014213

Device Name: INFINITY Gateway Suite

Indications for Use:

Siemens MultiView WorkStation, INFINITY Network and Remote Display are indicated for use as a central monitoring device, communications network, and remote display for Siemens Patient Monitoring Systems and recorders.

The Infinity Gateway Suite software applications are intended to provide clinicians with the capability of viewing patient data remotely via the Infinity Network and for the data exchange of select clinical and administrative information between the Infinity Network and the hospital network.

MRI Compatibility Statement:
The MultiView WorkStation, Infinity Network and Gateway Suite are not compatible for use in a MRI magnetic field.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Division of Cardiovascular & Respiratory Devices
510(k) Number K014213